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L2: Entry 1 of 16

File: USPT

Jul 11, 2000

DOCUMENT-IDENTIFIER: US 6087329 A

TITLE: CD40 ligand polypeptide

## DEPR:

These data indicate that the interaction of CD40 with its ligand is the principal molecular interaction responsible for T cell contact dependent induction of B cell growth and differentiation to both antigen-specific antibody production and polyclonal Ig secretion. As such, these data suggest that antagonists of this interaction, by soluble CD40, CD40/Fc fusion protein and possibly soluble CD40-L (monomeric), will significantly interfere with development of antibody responses. Therefore clinical situations where CD40, CD40/Fc fusion proteins and soluble CD40-L are suitable include allergy, lupus, rheumatoid arthritis, insulin dependent diabetes mellitus, and any other diseases where autoimmune antibody or antigen/antibody complexes are responsible for clinical pathology of the disease. Moreover, membrane-bound CD40-L or oligomeric soluble CD40-L will be useful to stimulate B cell proliferation and antibody production. As such, these forms of CD40-L are most useful for vaccine adjuvants and as a stimulating agent for mAb secretion from hybridoma cells.

## DEPR:

A second experiment was carried out using different lots of reagents and varying the concentrations of the CD40-L. A significant difference between the control mice and the mice treated with CD40 ligand was not observed at day 7, however, CD40-L did enhance the day 14 response. Additional experiments to address the use of CD40-L will include an analysis of different antigens as well as the use of different adjuvants and delivery systems.

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L2: Entry 10 of 16

File: USPT

Oct 5, 1999

DOCUMENT-IDENTIFIER: US 5962406 A

TITLE: Recombinant soluble CD40 ligand polypeptide and pharmaceutical composition containing the same

## DEPR:

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L2: Entry 16 of 16

File: USPT

May 5, 1998

DOCUMENT-IDENTIFIER: US 5747024 A

TITLE: Vaccine adjuvant comprising interleukin-15

**BSPR:**

The invention is directed to a composition that is capable of augmenting the immunogenicity of a vaccine. The composition, or adjuvant, is administered to a mammal in need thereof in sequential or concurrent combination with the vaccine antigen. In particular, the adjuvant is a cytokine known as interleukin-15 ("IL-15"). IL-15 is a recently discovered cytokine, and is a potent T cell growth factor. IL-15 can cause the proliferation and differentiation of T cells in vitro and can augment T cell mediated immune response in vivo. In addition, IL-15 has been shown to stimulate the induction of B cell proliferation and differentiation. The proliferation and differentiation of antigen specific T cells and B cells can augment the protective immunity for a particular antigen. These properties of IL-15 make it a suitable adjuvant for a variety of vaccines wherein augmentation of the immune response to the antigen is desired. Administration of IL-15 in concurrent or sequential combination with a vaccine will prompt an enhanced immune response against the vaccine. Further included in the invention are compositions that comprise such an immunogenicity-augmenting amount of IL15 in combination with at least one other vaccine adjuvant, such as, for example, IL-2, IL-10, GM-CSF, G-CSF and CD40 ligand. Methods of vaccination that provide for the administration of an immunogenicity-augmenting amount of IL-15 and an immunogenicity-augmenting amount of another vaccine adjuvant are also provided by the invention.

**DEPR:**

IL-15 also can be administered in combination with at least one other vaccine adjuvant. Many vaccine adjuvants exist and would likely be suitable for use in combination with IL-15, for example, cytokines are particularly preferred vaccine adjuvants. More preferred adjuvants include granulocyte-macrophage colony stimulating factor (GM-CSF), granulocyte colony stimulating factor (G-CSF), IL-2, IL-4, IL-10 and CD40-ligand. Preferred vaccine adjuvants that can be administered with IL-15 and the vaccine are CD40-ligand and GM-CSF. Most preferred is GM-CSF. The additional adjuvant also can be administered in sequential or concurrent combination with IL-15 or the vaccine.

**CLPR:**

4. A method according to claim 3, wherein the additional vaccine adjuvant is selected from the group consisting of CD40-ligand, GM-CSF, G-CSF, IL-2, IL-4 and IL-10.

**CLPR:**

9. A composition according to claim 8, wherein the additional vaccine adjuvant is selected from the group consisting of CD40-ligand, GM-CSF, G-CSF, IL-2 and IL-10.